K101787

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OCT 8 2010

510 (k) SUMMARY
(per 21 CFR 807.92)

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6146 Fax: 847-534-6111
Date Prepared:	September 22, 2010
Trade Name:	DuoLink II
Common Name:	Composite Luting Cement
Product Code:	EMA
Classification/Name:	Dental Cement **Class II per 21 CFR 872.3275**
Predicate Devices:	Duolink by Bisco, Inc., Schaumburg IL K934596 Calibra by Dentsply Intl., York PA K040906 Self-Adhesive Luting Cement by DMG USA Inc., Ayer MA K093338

Description of the Applicant Device/Indications for use:

DuoLink II is a dual-cured, radio-apparent composite luting cement.

The indications of use of **DuoLink II** are to cement:

1. All indirect restorations (ie. crowns, bridges, inlay, and onlays fabricated from metal composite, porcelain, ceramic, zirconia, alumina, etc)
2. All endodontic posts (ie. fiber, composite, and metal)
3. All abutments (ie. screws)

BISCO, Inc.
1100 W. Irving Park Road
Schaumburg, IL 60193 U.S.A.

800-247-3368 or 847-534-6000
Fax: 847-891-5049
www.bisco.com

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510 (k) SUMMARY (continued)

Technological Characteristics

All chemical components of **DuoLink II** are based upon industry standard monomer chemistry and are found in the legally marketed predicate device DuoLink (K934596). A comparison of the technological characteristics to the predicate devices is summarized below.

Chemical Composition	DuoLink K934596	Calibra (K040906)	Self Adhesive Luting Cement K093338	DuoLink II
Self-Cure	X	X	X	X
Light-Cure	X	X	X	X
Glass Filled	X	X	X	X
Methacrylate resin based	X	X	X	X
Self-Adhesive			X	

Performance Data

Physical/mechanical properties of Duo-Link II were tested using ISO 4049:2009. The Information provided in this 510(k) of **DuoLink II** as compared to Calibra (K040906) demonstrates that **DuoLink II** is performs as well as or better than Calibra. A comparison of the physical/mechanical properties is included in the chart below:

Physical / Mechanical Property Comparison	DuoLink K934596	Calibra (K040906)	DuoLink II
Medium viscosity dispensable material	X	X	X
Radio-apparent	X	X	X

Biocompatibility

Biocompatibility testing was conducted to determine the safety of the **DuoLink II** using FDA guidelines and ISO 10993-1. Cytotoxicity using the ISO Agarose Overlay Method determined t hat the samples showed no evidence of causing any cell lysis or toxicity and met the requirements of the test. The conclusion of the safety evaluation and subsequent cytotoxicity testing is that **DuoLink II** is safe for its intended use.

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510 (k) SUMMARY (continued)

Conclusion

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to other the legally marketed devices: Duolink (K934596), Calibra (K040906), and Self Adhesive Composite Luting Cement (K093338). It is concluded that the information, formulation, physical properties, and biocompatibility, supplied in this submission has proven the safety and efficacy of this product.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Schiltz-Taing
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumberg, Illinois 60193

OCT 8 2010

Re: K101787
Trade/Device Name: DuoLink II
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: September 28, 2010
Received: September 29, 2010

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K101787

Device Name: _____

Indications for Use:

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1. All indirect restorations (ie. crowns, bridges, inlay, and onlays fabricated from metal composite, porcelain, ceramic, zirconia, alumina, etc)
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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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